

REMARKS1. CLAIM REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner rejected claims 33, 35-36, 39-43, 45-47, 50-52, and 56-57 under 35 U.S.C. § 112, first paragraph because the specification allegedly did not describe the invention sufficient to demonstrate that the inventors had possession of the claimed invention. The Applicants respectfully traverse the present rejection.

The Examiner maintains the rejection allegedly because there is an "absence of a definition in the instant specification of the term accessory molecule" and because "the genus of said accessory molecules that would be effective in the recited synthetic antigen presenting cell, would not be readily apparent to one of skill in the art".

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48

USPQ2d 1641, 1647 (1998).

The Examiner's assertion that there is an "absence of a definition ... of the term accessory molecule" is without merit. The specification discloses that accessory molecules include, "costimulatory molecules, adhesion molecules, and survival molecules, [and] are effective in concert with the MHC class II heterodimer complexed with peptide in activating CD4⁺ cells...". See, e.g., page 21, lines 4-9. The specification further provides specific examples of each type of accessory molecule (see below). Thus, the meaning of "accessory molecule" in the context of the invention is disclosed in the specification.

The Examiner's assertion that, "the genus of said accessory molecules...would not be readily apparent to one of skill in the art" is also without merit. As mentioned above, the accessory molecules of the present invention are, "effective in concert with the MHC class II heterodimer" in activating CD4⁺ cells. The accessory molecules were well known to one skilled in the art at the time the present application was filed. See, e.g., Mondino et al. (1994) Leukocyte Biology 55:805-815. Furthermore, the specification discloses specific examples of useful accessory molecules including: costimulatory molecules such as B7.1 and B7.2, adhesion molecules such as intercellular cell adhesion molecule-1 (ICAM-1) and lymphocyte function-associated antigen-3 (LFA-3), and survival molecules such as Fas ligand (FasL) and CD70. See, e.g., page 6, lines 19-23; page 21, line 4 through page 24, line 2; and page 72, line 14 through page 78, line 16 of the specification. Still further, the specification discloses an actual reduction to practice of the present invention. See, e.g., page 83, line 10 through page 87, line 21 including the results

displayed in Table 1 on page 84. Based upon the disclosures in the specification, the knowledge available in the art, and the reduction to practice of the present invention; one skilled in the art can reasonably conclude that the inventors were in possession of the claimed invention at the time the invention was filed. The Examiner has failed to make a prima facie case that the inventors did not have possession of the claimed invention because the genus of accessory molecule is disclosed in terms of function and with numerous examples expressly recited, as discussed herein above. The Applicants respectfully request that the present rejection be withdrawn.

2. CLAIM REJECTIONS UNDER DOUBLE PATENTING

Claims 33, 35-36, 41-43, 44-47, 50-52, and 56-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,355,479.

Upon notification of allowable subject matter, Applicants will submit a Terminal disclaimer as requested by the Examiner.

3. CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b)

A. Galvin et al.

Claims 33, 35-36, 41-42, and 44-47 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Galvin et al. (1992) Journal of Immunology 149:3802-3808. The present rejection is respectfully traversed.

The claimed invention is directed to a synthetic antigen

presenting matrix comprising, in part, an extracellular portion of a recombinant MHC class II heterodimer (emphasis added). Galvin et al. does not teach an extracellular portion of a recombinant MHC class II heterodimer. Therefore, Galvin et al. cannot anticipate the claimed invention.

The claimed invention is further directed to a synthetic antigen presenting matrix comprising, in part, an extracellular portion of at least one recombinant accessory molecule (emphasis added). Galvin et al. does not teach an extracellular portion of at least one recombinant accessory molecule. Therefore, Galvin et al. cannot anticipate the claimed invention.

B. Baskar et al.

Claims 33, 35-36, 41-42, and 44-47 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Baskar et al. (1993) Journal of Immunotherapy 14:209-215.

The claimed invention is directed to a synthetic antigen presenting matrix comprising, in part, an extracellular portion of at least one recombinant accessory molecule (emphasis added). Baskar et al. does not teach an extracellular portion of at least one recombinant accessory molecule. Therefore, Baskar et al. cannot anticipate the claimed invention.

Neither Galvin et al. nor Baskar et al. teach each and every element of the claimed invention. Therefore, Galvin et al or Baskar et al cannot anticipate the claimed invention and the present rejection should be withdrawn because

CONCLUSION

The Applicant respectfully requests that the Examiner enter the present response herein, withdraw all claim rejections, and place the claims in condition for allowance.

The Examiner is requested to contact the representative for the Applicants, to discuss any questions or for clarification. If there are any further fees associated with this response, the Director is authorized to charge our Deposit Account No. 19-0962.

Respectfully submitted,

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Date

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